UNITED STATES DEPARTMENT OF COMMERCE
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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
08/913,811	09/24/97	SUGIHARA H	356972020100

HM12/1222

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EXAMINER	
BASKAR, P	
ART UNIT	**PAPER NUMBER**
1645	13

DATE MAILED: 12/22/99

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.	Applicant(s)
08/913,811	SUGIHARA HIROKAZU
Examiner	**Group Art Unit**
Padma Baskar	1641

☒ Responsive to communication(s) filed on *Sep 28, 1999*

☒ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claim

☒ Claim(s) *1-15* is/are pending in the applicat

Of the above, claim(s) *1-11* is/are withdrawn from consideration

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) *12-15* is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☒ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

DETAILED ACTION

1. Applicant's amendment filed on 9/28/99 is acknowledged. Claims 12 and 13 have been amended and new claims 14 and 15 have been entered. Claims 1-15 are pending. Claims 1-11 are withdrawn from consideration as drawn to a non-elected invention. Currently claims 12-15 are under consideration.

2. Examiner has withdrawn 35 U.S.C.112, second paragraph rejection of claim 12 for the recitation of "judging from ---on the tissue or cell" in view of applicant's amendment to the claim.

3. Examiner has withdrawn 35 U.S.C. 102(b) rejections as anticipated by Nisch et al 1994 in view of applicant's arguments.

NEW REJECTIONS NECESSITATED BY AMENDMENT

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 12-15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 12 is rejected as being vague and indefinite for the recitation of "chemical substance" twice in the claim (line 12).

Claim 13 lacks antecedent basis for "said' chemical substance.

Claim 14 and 15 are rejected as being vague and indefinite for the recitation of "arbitrary concentration". The Webster's II New Riverside University Dictionary meaning of arbitrary is "Determined by impulse or whim". Therefore, it is unclear what are the metes and bounds of arbitrary concentration?

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 12 -15 are rejected under 35 U.S.C. 102(b) as being anticipated by Giaever et al (U.S. Patent 5187096).

Giaever et al describes a method which comprises a detector for detecting electrical properties of endothelial cells when chemical substance thrombin is exposed to the cultures in Figure 9 which is observed (i.e visible property). He further describes a testing device that comprises electrical measurement portion (i.e visible detection portion) (Figure 3, data acquisition, figure 4, figure 5, figure 6 etc). The prior art anticipates the claimed invention.

Applicant argues that Giaever et al's device is of a type that is not suitable for use with a tissue but instead is applicable only for a soup of cells and no two electrodes of Giaver et al are able to access a single slice of tissue.

Examiner would like to bring applicant's attention that claims are neither directed to a single slice of tissue nor two electrodes are able to access to a single slice of tissue. Further more, the apparatus and method of Giaever invention not only measures cultured cells but also cells that are attached to surfaces can be followed continuously and in real time. In other words, the invention can detect and measure cell attachment, cell spreading, lateral motion of cells, impedance of cell sheets, areas involved in adhesion plaques, cell-substrate spacing and vertical cell motion. (Column 3, lines 23-30). This apparatus and method can be used with human and murine fibroblasts and bovine endothelial cells (tissue) to changes in the physical environment and to drugs and other biological active compounds, under normal culture conditions, fibroblasts and endothelial cells form a sheet of tissues in culture. And also the electronics of the invention are connected to arrays of electrodes. (Column 3, lines 31--67) and multiple electrodes can be used with in the same culture chamber. Thus the prior art anticipates the claimed invention.

Claims 12 -15 rejected under 35 U.S.C. 102(b) as being anticipated by. Suzuki et al (U.S.Patent 4288544). Suzuki et al describe a method which comprises a detector for detecting electrical properties of different microorganisms when cultured with different media in Table 1, 2, 3, 4, 5, which is observed (i.e visible property). He further describes a testing

device comprising electrical measurement portion (i.e visible) visible detection portion (Figure 1 and 2 potentiometer and recorder). The prior art anticipates the claimed invention.

Applicant argues that Suzuki et al fails to show a multiple electrode device which is capable of contact with a tissue sample.

Examiner points out that Suzuki et al suggests that those skilled in the art can simplify remodel the device, such as to use with tissue.

Claims 12 -15 rejected under 35 U.S.C. 102(b) as being anticipated by Nicander et al 1995 (British Journal of Dermatology , 132; 718-724) .

Nicander et al discloses electrical impedance measured to five skin depths in mild irritant dermatitis induced by sodium lauryl sulphate. He uses electrical impedance measurements and also correlates those measurements with histological and visual scoring.(abstract). The prior art anticipates the claimed invention.

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor

and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103© and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

Claims 12-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nisch et al (Biosense.Bioelect 1994, 9:737-741). Nisch et al describes a method which comprises a detector for detecting electrical properties of neuronal activity in vitro . He measures a detectable electrical signal before and after stimulation in figure 7 which is observed (i.e visible property). He further describes a testing device comprising electrical measurement portion (i.e visible) visible detection portion (Figure 3-monitor, figure 4, figure 5, figure 6 etc). However, Nisch et al does not teach that the method and device are used for tissues. However, Stedman's Medical Dictionary defines tissue as "a collection of similar cells and the intercellular substances surrounding them . There are four basic tissues in the body: 1) epithelium; 2) the connective tissue, including blood, bone, and cartilage; 3) muscle tissue; and 4) nerve tissue. In addition, while specification puts forth preferred embodiments, the specification does not define and restrict the term tissue to a particular embodiment. Therefore , based on Stedman's Medical Dictionary the term tissue encompasses blood , which are single cells floating.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to modify the Nisch et al method and device with a reasonable expectation of success because use of this method and device for tissue culture system are readily available. An artisan of ordinary skills would have been motivated to make such a device and method for measuring the

electrical properties of tissues before and after addition of medicine or drugs because it would have helped in measuring the electrical properties of tissues before and after addition of medicine or drugs as taught by Nisch et al.

7. Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file. Applicant has submitted the search report of PCT/JP97/00153. However, these references were not provided. If applicant desires these references to be considered by the examiner, such should be provided as well as form 1449.

8. Since the restriction requirement is based on the special technical feature and over prior art, examiner made this restriction as final in the previous office action. Applicant's arguments filed 9/28/99 have been fully considered but they are not deemed to be persuasive. This is not found persuasive because the examiner believes that the application has been filed under 35 U.S.C. 371, "Lack of Unity" practice is being followed

Although the applicant's above concept may link the three inventions, such concept does not constitute a "special technical feature" as defined by PCT Rule 13.2 (37CFR1.475(a)). "The expression "special technical features" shall mean those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art." Specifically US.Patent No 5187096, EPO 585933 and Nisch et al (Biosense.Bioelect 1994, 9:737-741) teach this concept, therefore it does not constitute" a special technical feature" by definition. Therefore, lack of unity is present.. The requirement is still deemed proper and is therefore made FINAL.

9. No claims are allowed in the present application.

Conclusion

10. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See M.E.P. § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Parma Boskier whose telephone number is (703) 308-8886. The examiner can normally be reached on Monday through Friday from 6.30 AM to 4 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James House, can be reached on (703) 308-4027. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Padma Baskar Ph.D.

12/14/99

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